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GOOD MEDY ENTERPRISE LTD.
1FL. NO. 72 ALLEY 33. LANE 514. JONGIENG RD.
SHINGJUANG CITY. TAIPEI.TAIWAN 242. R.O.C
Tel: 886-2-29044502 Fax: 886-2-29043278
E-mail: ez0888@ms56.hinet.net http://www.probecover.com.tw

JUN 14 2006

" 510(k) SUMMARY "

Submitter's Name: *GOOD MEDY ENTERPRISE LTD.*
1FL,NO.72,ALLEY33,LANE514,JONGIENG RD,SHINGJUANG CITY, TAIPEI, TAIWAN, 24255, R.O.C.

Date summary prepared: April 2, 2006

Device Name:

- Classification name: *Thermometer, Electronic, Clinical*
- Classification number: *FLL, Class II*
- *Regulation Number*: *880.2910*
- Proprietary name: *GOOD MEDY, Disposable Thermometer Sheaths*
- Common name of device: *Disposable Thermometer Sheaths*
- Predicate Device: *Sanitherm Oral Disposable Thermometer Sheaths, K983406*

Indications for Use:

The devices are intended for use as a barrier that is used as an accessory to oral or rectal for digital thermometers. These sheaths are non-sterile and intended for single patient use only.

Description of the device:

The disposable thermometer sheaths are plastic coverings used for either oral or rectal for digital thermometer. The products and its packaging are non-sterile and latex-free.

Material Testing:

1.Material test report by SGS.

2.ISO10993-5 and ISO10993-10 for biocompatibility test by Biomaterials Laboratory of National Chung Hsing University in Taiwan.

Legally marketed device for substantial equivalence comparison:

Sanitherm Oral Disposable Thermometer Sheaths, K983406.

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Summary for substantial equivalence comparison:

The new devices, GOOD MEDY Disposable Thermometer Sheaths, are substantially equivalent to the predicate devices: Sanitherm Oral Disposable Thermometer Sheaths, K983406. The intended use of the two devices is the same, and the overall dimensions are similar. The two devices also had passed the biocompatibility test by ISO10993, same non-sterile and latex-free.

Thus the new devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2006

Dr. Jen Ke-Min
Official Corrsepondent
Good Medy Enterprise, Limited
1 Fl. No. 72, Alley 33, Lane 514, Jongieng Road
Shingjuang City, Taipei,
CHINA (Taiwan) 24255

Re: K061007
Trade/Device Name: Good Medy, Disposable Thermometer Sheaths
Regulation Number: 21 CFR 880.2910
Regulation Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL
Dated: April 2, 2006
Received: April 11, 2006

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

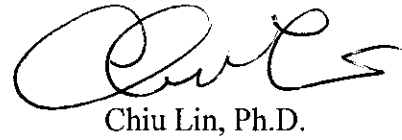
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061007

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Indications for Use

510 (K) Number (If Known): K

Device Name: *GOOD MEDY, Disposable Thermometer Sheaths*

Indications for Use:

The devices are intended for use as a barrier that is used as an accessory to oral or rectal for digital thermometers. These sheaths are non-sterile and are intended for single patient use only.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(K) Number: K061007